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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,785	09/12/2003	Joern Moeckel	2924-216	5867

6449 7590 11/24/2008

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EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/660,785	MOECKEL ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-35 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-35 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-20-2008 has been entered.

Pursuant to amendment, claims 22-35 and 37-43 are pending in this action.

Response to Arguments

Applicant's arguments with respect to claims 22-35 and 37-43 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-35 and 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/09785 (IDS filed 05/19/2005) in view of Getz et al in Clinical Pharmacology & Therapeutics, US 5,639,476 and Canadian Patent 2,149,052.

The WO reference teaches dosage forms of bisphosphonates, specifically risedronate. The reference recognizes that risedronate and related bisphosphonates

irritate the esophagus. The WO reference thus teaches dosage forms that have the bisphosphonate in the core, and a coating that is free of bisphosphonate. The coatings used are enteric, that is, they do not dissolve in the mouth, esophagus, or stomach, but do dissolve in the intestine. Thus, the WO reference avoids irritating the esophagus by delivering the bisphosphonate to the intestine. The drug is useful for treating conditions such as osteoporosis, Paget's disease, and others.

What is lacking in the WO reference is:

1) a teaching of releasing the drug in the stomach

2) a teaching to use the instantly claimed polymers or polymer/pore former combinations to do this, and

3) a teaching of ibandronate

The Getz reference teaches that the bioavailability of bisphosphonates in the intestine is very low.

The '476 patent teaches methods of controlling the delivery location and dissolution rate of dosage forms. The reference teaches that by altering the coating, such as by choosing an appropriate polymer and/or mixing the polymer with pore formers, the artisan can alter the location in which the drug is released. By choosing a polymer that dissolves at a particular pH, the artisan will obtain a dosage form that releases in the part of the body having that pH. For example, Eudragit RL/RS (polymers of instant claims) may be mixed to achieve the desired release profile. Alternatively, the artisan can use a pore former to control the release profile. One exemplary polymer is hydroxypropylmethyl cellulose (methylhydroxypropyl cellulose).

An exemplified pore former is lactose. Col. 8-11. Note that Applicants, on pages 11-14 of their response filed 8/20/2008, argue (in a different context) that the '476 patent would teach the artisan how to deliver, for example, 30% or more of a drug to the stomach, if the artisan had some reason to desire such delivery.

The Canadian Patent teaches that ibandronate is useful for treating bone disorders, such as osteoperosis. Note that ibandronate appears useful for treating the same disorders that risendronate treats. Ibandronate is also taught to be a bisphosphonate, similar to risendronate.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to deliver bisphosphonates, such as ibandronate, to the stomach and to use the instantly claimed polymers or polymer/pore former combinations to accomplish this. The WO reference teaches that bisphosphonates irritate the esophagus, and the Getz reference teaches that they are very poorly absorbed from the small intestine. By process of elimination, the only place left for an oral dosage form to deliver bisphosphonates is the stomach. Clearly, the artisan would be motivated to deliver bisphosphonates to the stomach, instead of the esophagus or intestine. The 476 patent teaches a method by which one could accomplish this, specifically by using the appropriate polymers or polymer/pore former combinations. As such, the artisan would find it obvious to use the polymers or polymer/pore former combinations of the 476 patent. Finally, the artisan would recognize that ibandronate and risedronate are both bisphosphonate drugs that are recognized as useful in treating the same disorders, and so would find it obvious to substitute one for the other.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burckhardt, "Ibandronate in Oncology" 1997 is cited for its explanation of the teachings of Getz. Getz is somewhat complex; Burckhardt indicates what the person of ordinary skill in the art would understand Getz to teach by citing Getz for the proposition that "[bisphosphonates have] exteremely low intestinal absorption rate[s]." Page 1696.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618